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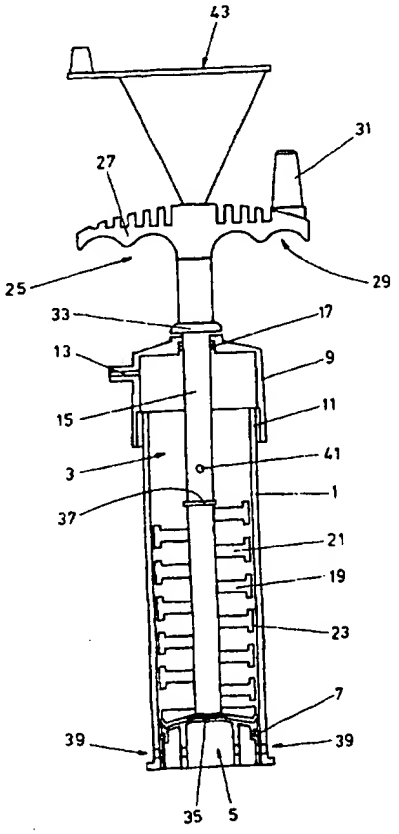
(54) Title: MIXING BONE CEMENT

(57) Abstract

A device for mixing bone cement comprises a mixing chamber with a lid, a mixing member mounted on a shaft extending out of the mixing chamber through an opening in the lid, by which the member can be (i) moved axially within the mixing chamber, and (ii) rotated about the axis provided by the shaft, and a handle for the mixing member having a grip portion extending laterally of the said shaft and a formation on the grip portion of the handle spaced apart from the shaft. The formation can be a protrusion extending from the grip portion of the handle in a direction generally parallel to the axis of shaft, so that it can be gripped by the user of the device to cause the grip portion to rotate around the axis.



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MIXING BONE CEMENT

This invention relates to a device for mixing bone cement.

Bone cement is generally supplied as two separately packaged reactive components which are mixed to form a cement. The cement is malleable initially after mixing, but hardens as the components react together. The cement can be worked into contact with the bone to which is to be secured when still malleable, for example by injection using a syringe into a bone cavity.

The cement components generally comprise a powder and a liquid. For example, a cement might comprise liquid methyl methacrylate monomer and poly(methyl methacrylate) and/or styrene methyl methacrylate copolymer in powder form. Other combinations of liquid monomeric species with powders comprising one or more different types of polymer can be used. Thorough mixing of the components is essential in order for the bond provided by the cement to have optimum strength and life. Mixing of the components generally involves adding the components sequentially to a mixing chamber. This results in one of the components resting or "floating" on the other component. Mixing then requires relative vertical movement of the cement components so that there is a substantially constant distribution of powder and liquid throughout the depth of the chamber, before powder and liquid are mixed intimately together.

The mixing of the components should of course take place under sterile conditions, and preferably under conditions which minimise air bubbles or other voids in the mixed cement.

WO-A-93/22041 discloses a device for mixing bone cement which includes a lid having an aperture in it which can receive an agitator rod. The rod can be attached to an agitator which can be moved axially within a mixing chamber (provided by a syringe

body) to cause cement components within the chamber to mix. The rod has a handle at its outer end by which the rod can be gripped to move the agitator axially in the chamber.

The present invention provides a device for mixing bone cement in which the mixing member can be manipulated on a shaft by means of a handle with a lateral grip portion for moving the mixing member up and down to distribute bone cement components evenly throughout the depth of the mixing chamber, and a formation on the grip portion which facilitates rotation of the mixing member.

Accordingly, in one aspect, the invention provides a device for mixing bone cement which comprises:

(a) a mixing chamber with a lid;

(b) a mixing member mounted on a shaft extending out of the mixing chamber through an opening in the lid, by which the member can be (i) moved axially within the mixing chamber, and (ii) rotated about the axis provided by the shaft; and

(c) a handle for the mixing member having a grip portion extending laterally of the said shaft and a formation on the grip portion of the handle spaced apart from the shaft.

The device of the present invention facilitates thorough mixing of bone cement components in a mixing chamber, by an initial mixing step which involves axial movement of the mixing member in the mixing chamber, with or without a simultaneous rotatory component of motion. This can make the distribution of bone cement components, added sequentially to the chamber so that they are arranged in layers, relatively uniform throughout the depth of the chamber. After the axial movement step, the rotation of the mixing member facilitated by the formation on

the grip portion can ensure thorough mixing of the cement components with uniform dispersion of a particulate component through the other component or components, for example of a particulate component in a liquid component.

Preferably, the handle has two (or more) grip portions, extending laterally of the shaft on opposite sides thereof. The provision of two or more grip portions spaced apart around the shaft enables the handle to be gripped so as to move the mixing member axially, with or without a rotatory component of motion, within the mixing chamber without large transverse forces applied thereto.

Preferably, the formation that is provided on the grip portion of the handle spaced apart from the shaft, is a protrusion that can be gripped by the user of the device to cause the grip portion to rotate around the axis provided by the shaft. The protrusion extends from the grip portion of the handle in a direction generally parallel to the axis of shaft. It need not extend precisely parallel to the shaft: for example the angle between the axis of the shaft and the axis of the protrusion might be as much as 15°, 25° or more. Preferably, the protrusion is able to rotate on the grip portion of the handle.

In alternative constructions, the formation might be for example a recess by which the grip portion can be gripped conveniently to cause it to rotate.

Preferably, the mixing member includes at least one laterally extending paddle located at or towards the end of the mixing member in the mixing chamber. Preferably, there are at least two paddles that are spaced apart along the shaft of the mixing member. The design of the paddles should generally be such that, on rotation of the mixing member, substantially all of the cement components are contacted and moved, and thereby mixed. Preferably, such spaced apart paddles are offset relative to one another around the shaft of the mixing member.

At least one of the paddles can be non-planar when viewed in a direction parallel to the shaft so that, when the mixing member is moved axially, the paddle imparts a lateral movement to cement that it contacts. This can facilitate thorough mixing of the cement components in the first, axial movement phase of using the device.

The paddles can be provided as separate members that are individually attached to a shaft extending throughout the mixing chamber. In another construction, two or more paddles may be connected or otherwise attached to one another (for example by being formed as a single article by moulding), and then connected to the shaft which need not then extend throughout the mixing chamber. The paddles can be formed with the shaft, for example by a moulding operation.

Preferably, the device of the invention includes a lid on the mixing chamber, having an aperture in it through which the shaft of the mixing member extends. The lid can include an appropriate seal between it and the shaft to minimise leakage of cement components through the aperture. The seal might be provided by a gasket (for example formed from a material with elastomer properties such as natural rubber, nitrile rubber, or a silicone rubber) in the aperture which engages the shaft with a snug sliding fit.

The mixing chamber can have a port which can be connected to an appropriate extractor, for example a vacuum pump, by which vapours can be removed from the chamber, minimising hazards to the operator of the device. The port can conveniently be provided in the lid of the chamber. Appropriate filters can be provided to control the extraction of particulate material from the mixing chamber when connected to the extractor.

Preferably components of the device such as the mixing chamber and the mixing member are formed from polymeric materials. It can be preferred to form the mixing chamber from a translucent

or more preferably a transparent material, such as a polyester or a polycarbonate. This has the advantage of enabling the mixing process to be observed visually. The handle and the paddles on the mixing member can be formed from a polyolefin such as a polyethylene or a polypropylene, preferably by a moulding process. The shaft of the mixing member can also be formed from a polymeric material although use of a metal (for example aluminium or an alloy thereof) can be preferred because of the greater rigidity that can be available from it.

Preferably, the shaft of the mixing member is hollow. This can enable bone cement components to be mixed in the chamber can be introduced into the chamber through the shaft. An appropriate port can be provided in the handle if necessary if the handle is provided on the top of the shaft.

Preferably, the mixing chamber includes a piston which can be moved axially through the chamber to extrude mixed cement from the chamber as from a syringe. Preferably, the chamber is arranged so that the mixed cement is extruded through the end thereof through which the shaft of the mixing member extends. For example, the mixing member may be removable from within the mixing chamber so that the cement can be extruded from the chamber through the aperture previously occupied by the shaft. An appropriate slot can be provided for this purpose at the end of the mixing chamber to which the lid is attached. In another construction, the mixing member can be removed from the mixing chamber together with an end cap through which it extends, and a nozzle can be positioned on the chamber for extrusion of the mixed cement.

It can be preferred for the piston to be restrained from axial movement within the chamber until it is required to extrude the cement from the chamber, for example by means of a pin which extends across the chamber to tie the piston to the chamber walls.

When the cement is extruded from the mixing chamber through an aperture in the cap, a port in the cap for connection to an extractor can facilitate extrusion of cement with minimum air or other voids in it, by maintaining the chamber at reduced pressure during the extrusion step.

The piston preferably has associated with it a device for ensuring that cement is not retained in a nozzle extending from the outlet of the mixing chamber, of the kind disclosed in EP-A-108584.

The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is an sectional elevation of one embodiment of the device; and

Figure 2 is an isometric view of a number of components of the device.

Referring to the drawings, Figure 1 shows a cylindrical body 1 defining a mixing chamber 3. The chamber 3 is sealed at its lower end by the head of a piston element 5. A nitrile rubber "O" ring 7 seals the gap between the wall of the cylinder 1 and the piston head 5. The other end of the chamber is sealed by a lid 9 which surrounds the end portion 11 of the cylinder 1. The lid 9 is provided with a port 13 allowing access to the chamber 3.

The lid 9 is also provided with a central aperture which receives an axially extending shaft 15 of the mixing member. The shaft is sealed relative to the lid by means of an "O" ring 17.

The shaft 15 provides a mounting for a series of radially extending paddle elements 19. These extend over substantially the full width of the chamber 3. The paddles consist of stem

portions 21 and head portions extending substantially parallel to the axis of the shaft 23.

The shaft 15 is connected to a handle 25 which provides two laterally extending grip portions 27 each provided with indents 29 which receive the fingers of the operator in use. These grip portions 27 facilitate axial movement of the shaft and mounted paddle elements relative to the cylinder in a reciprocating style motion.

The handle 25 is also provided with an additional formation 31 which facilitates rotation of the shaft 15 and stirrer elements mounted thereon. A collar 33 mounted on a shaft and the head surface 35 of the piston 5 control the position of the mixing elements when fully inserted into the chamber. The abutment of a further collar surface 37 with the top of the lid restrains the mixing unit relative to the chamber in the fully retracted position.

The piston head 5 and bottom walls of the cylinder 1 are provided with a through bore 39 which facilitates the insertion of a pin, 39, to fixedly locate the piston relative to the cylinder during the mixing stage.

The shaft 15 is hollow and is provided with a series of radially extending apertures 41 which are connected via the shaft to an inlet 43.

In use the piston head 5 is fixedly located by a pin 39 relative to the bottom end of the cylinder 1. The solid component, commonly in powder form, of the cement to be mixed is then placed in the cylinder. The mixing unit mounted on the head can then be engaged with the cylinder and the lid secured to give a good seal. The liquid component of the system can then readily be introduced by means of the hopper 43 down through the shaft 15 and out through apertures 41 into contact with the powder material already in the chamber.

The break off plug 44 provided on the hopper 43 can then be used to seal the inlet in the handle prior to mixing.

Axial motion of the mixing unit in a reciprocating manner causes the liquid and powder components to mix together. By rotating the mixing unit by handle 31 intimate mixing of the powder and liquid to give the desired cement can be effected.

Vapours produced during the mixing process can readily be extracted from the system by means of port 13 which can be connected to a vacuum pump for instance.

By forming the cylinder walls of a transparent material, such as polyester or polycarbonate, the extent and progress of the mixing stage can be observed.

Once the cement has been mixed adequately the mixing unit can be removed and an application head 50 attached to the cylinder. By removing the pin from apertures 39 the piston 5 can then be axially advanced along the cylinder 1 causing the cement to extrude through the applicator to the desired location.

CLAIMS:

1. A device for mixing bone cement which comprises:

(a) a mixing chamber with a lid;

(b) a mixing member mounted on a shaft extending out of the mixing chamber through an opening in the lid, by which the member can be (i) moved axially within the mixing chamber, and (ii) rotated about the axis provided by the shaft; and

(c) a handle for the mixing member having a grip portion extending laterally of the said shaft and a formation on the grip portion of the handle spaced apart from the shaft.

2. A device as claimed in claim 1, in which the formation is a protrusion.

3. A device as claimed in claim 2, in which the protrusion is mounted for rotation on the grip portion of the handle.

4. A device as claimed in any one of claims 1 to 3, in which the handle has two grip portions, extending laterally of the shaft on opposite sides thereof.

5. A device as claimed in any one of claims 1 to 4, in which the mixing member includes at least one laterally extending paddle located at or towards the end of the mixing member in the mixing chamber.

6. A device as claimed in claim 5, which includes at least two paddles which are spaced apart along the shaft.

7. A device as claimed in claim 6, in which the said paddles are offset from one another around the shaft of the mixing member.

8. A device as claimed in any one of claims 5 to 7, in which at least one of the paddles is non-planar when viewed in a direction parallel to the shaft so that, when the mixing member is moved axially, the said paddle imparts a twist to cement that it contacts.

9. A device as claimed in any one of claims 1 to 8, which includes a lid on the chamber, having an aperture in it through which the shaft of the mixing member extends.

10. A device as claimed in any one of claims 1 to 9, in which the shaft of the mixing member is hollow.

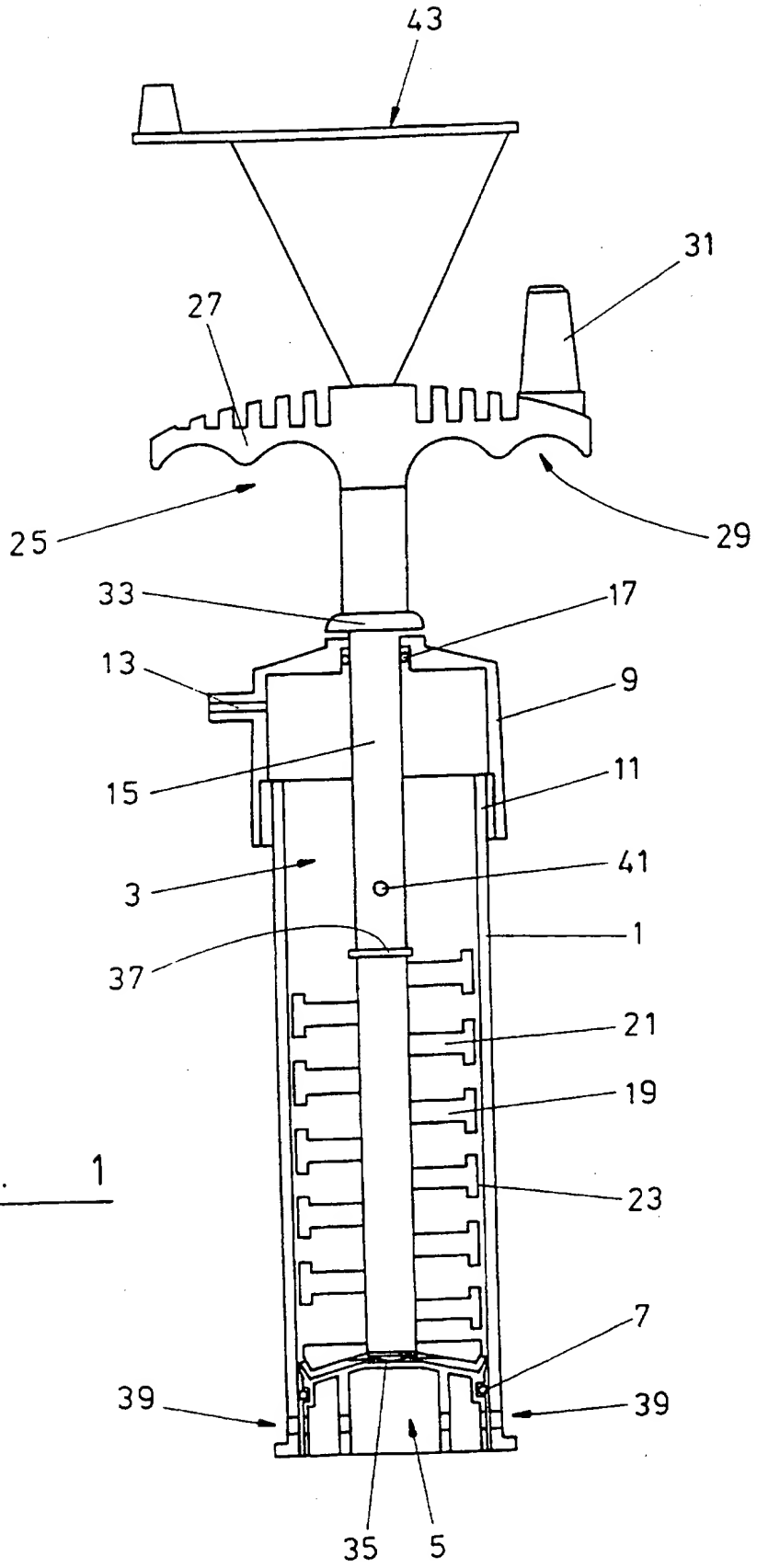

FIG. 1

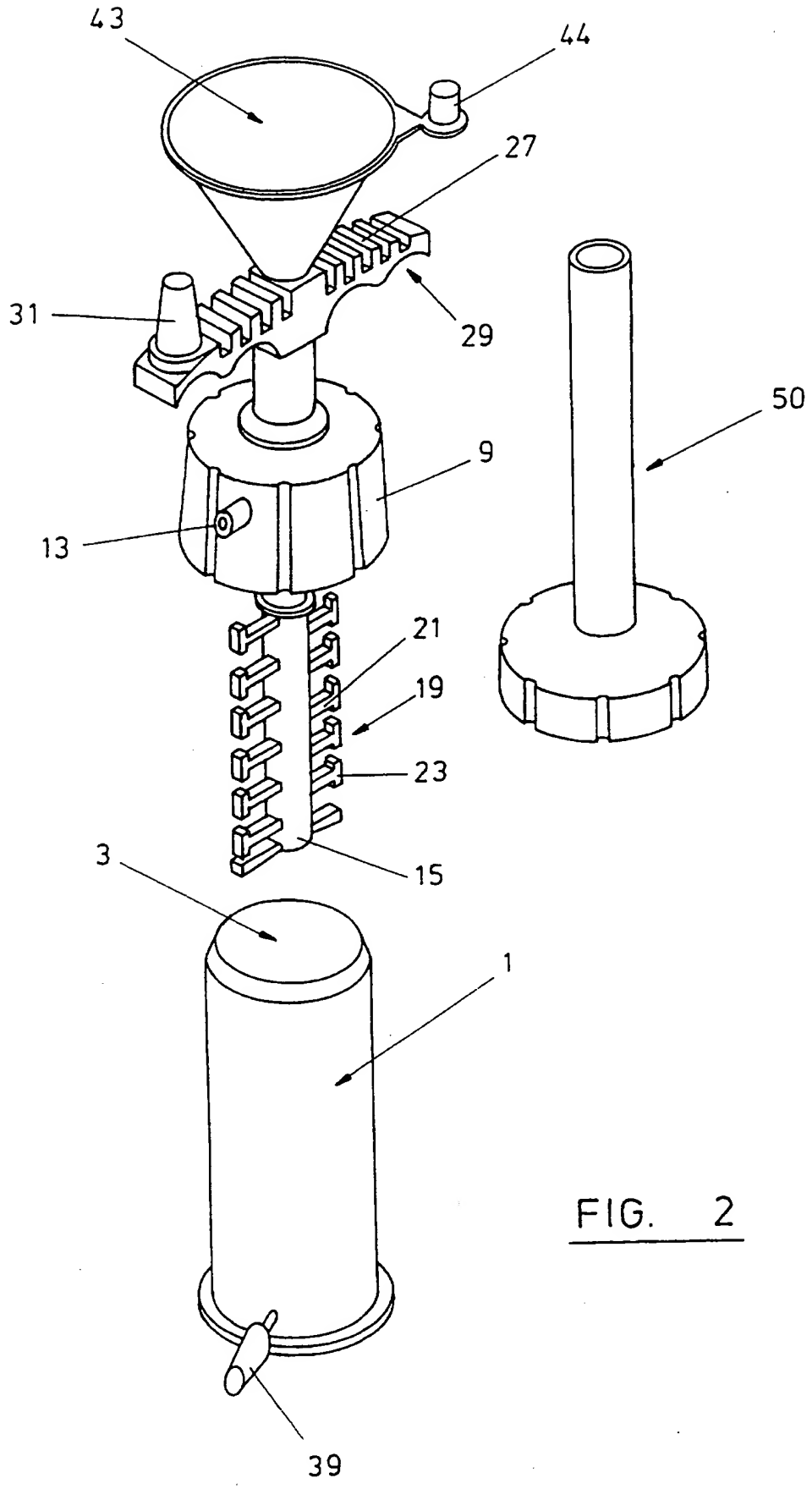

FIG. 2

INTERNATIONAL SEARCH REPORT

In ional Application No
PCT/GB 96/02997

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B01F7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B01F A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 676 655 A (HANDLER ISIDORE) 30 June 1987 see abstract; claims 1,2,14,15; figures 1-5,8,9 see column 5, line 64 - column 6, line 2 see column 6, line 40 - column 6, line 57	1-4,9
Y	---	5-8,10
X	EP 0 603 871 A (JANSSON VOLKMAR DR ;ZIMMER MARKUS DR (DE)) 29 June 1994 see abstract; claims 6-8; figure 2 see column 8, line 5 - column 8, line 55	1-3,5-9
Y	---	5-8
	US 3 358 971 A (STEINBOCK) 19 December 1967 see claims 1,2; figures 2,3,5 see column 1, line 9 - column 1, line 28 see column 3, line 18 - column 3, line 40	

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[X] Further documents are listed in the continuation of box C.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 4 799 801 A (BRUENING WERNER) 24 January 1989 see abstract; claim 1; figures 2-6 see column 2, line 33 - column 3, line 3	10
A	US 4 577 973 A (OCCELLI LUCIANO) 25 March 1986 see the whole document	

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